

REMARKS

Claims 11 – 44 are pending in the present application. No claims have been amended, canceled or added, leaving Claims 11 – 44 for consideration upon entry of the present response. Applicants respectfully request a withdrawal of the rejection and an allowance of the claims based upon the following remarks.

Claims Rejected under 35 U.S.C. § 102

Claims 11- 16, 21, 22, 24 – 31 and 34 – 44 are rejected under 35 U.S.C. §102 (b) as being anticipated by U.S. Patent No. 5,532,217 to Silver et al. (Silver). (Office Action dated 10-03-08, page 2)

In making the rejection, the Examiner has stated that the claims are drawn to a bioactive glass composite comprising biocompatible polymer and a bioactive glass. (Office Action dated 10-03-08, page 2)

In making the rejection, the Examiner has further stated that

[T]he '217 patent teaches a biological composite comprising mineralized fibers, bioactive glass materials and biocompatible polymers (abstract). The claims are drawn to a bioactive glass composite comprising biocompatible polymer and a bioactive glass. The '217 patent teaches a biological composite comprising mineralized fibers, bioactive glass materials and biocompatible polymers (abstract). The bioactive glass comprises a calcium and phosphate molecule (col. 2, lin. 40-49). The biocompatible polymers include gelatin, lanolin, or waxes (col. 2, lin. 50-53). The composite further comprises active agents such as hormones, enzymes and growth factors such as platelet-derived growth factors (col. 2, lin. 57-68). The material is used in bone repair therapies where the material is applied to treat bone defects (abstract, col. 2, lines 5-16). The fibers have the diameter from less than 1 micron to 500 microns (claims). The composite is formed in a method that includes mixing the calcium with phosphate, carrier compounds and extrusion at a temperature of 37 degrees Celsius (example). Regarding the composite at its ability to allow for the proliferation of stem cells, it is the position of the Examiner that these limitations are merely recitations of a future intended use.

The claims recite that the “cells when seeded” will proliferate, meaning the composite is not yet seeded and as such any proliferation would be an inherent feature of the composite. The composite of the instant claims comprises a bioactive glass materials and biocompatible polymers, while the '217 patent teaches an identical composite. Since a compound and its properties cannot be separated, and the composite of the '217 patent is

identical to that of the instant claims, it is the position of the Examiner that the composite of the '217 patent would also proliferate any seeded cells.

(Office Action dated 10-03-08, page 2)

To anticipate a claim under 35 U.S.C. § 102, a single source must contain all of the elements of the claim. *Lewmar Marine Inc. v. Barient, Inc.*, 827 F.2d 744, 747, 3 U.S.P.Q.2d 1766, 1768 (Fed. Cir. 1987), *cert. denied*, 484 U.S. 1007 (1988).

Claim 11 as previously amended is directed to a bioactive glass composite, comprising a biocompatible polymer, a bioactive glass including at least one calcium, and at least one phosphorous molecular species; the biocompatible polymer being reacted with the bioactive glass.

Silver teaches the mineralization of collagen fibers whereby collagen fibers are contacted with a solution of calcium and phosphate ions under conditions to effect nucleation and in-vitro growth of mineral crystals within and on the surface of the collagen fibers to form intact collagen fibers with sub-fibrillar substructure. (see Abstract and see Col. 2, lines 29 - 39) Silver teaches that minerals containing calcium and phosphate are in the form of brushite or hydroxyapatite. (See Col. 2, lines 44 – 46)

In the first instance, it is submitted that the Examiner appears not to have noticed biocomposite of the claimed invention is one that is produced as the result of a reaction between the biocompatible polymer and the bioactive glass. As noted above, Silver teaches the formation of crystals (from calcium ions and phosphate ions) that are embedded on the surface and within the fibrils of the collagen fibers. Silver does not teach that the biocompatible polymer is reacted with the bioactive glass. In particular, Silver does not teach that the crystals are reacted with the fibrils of the collagen fibers. The Examiner has also not pointed out where Silver teaches that the biocompatible polymer is reacted with the bioactive glass.

In his response dated 02-09-2009, the Examiner contends that the limitation of the “biocompatible polymer being reacted with the bioactive glass” is ignored because it is a product by process limitation and as such does not distinguish the claims over the prior art. (See Office Action dated 02-09-2009, page 6) The Examiner has further stated “[S]pecifically the limitation requires a processing step of “reacting” the two composite

materials, yet the claim is drawn to a product. (See Office Action dated 02-09-2009, page 6) The Applicants respectfully disagree.

In the first instance, the Applicants contend that numerous patents have been allowed by the U.S. Patent Office in the past with similar language. For example see Claim 10 of U.S. Patent No. 7,529,014 B2, which was allowed recently. A search for the use of the term “reacted” in the “claims” of U.S. Patents reveals 33,129 hits – indicating that the patent office has never had a problem with allowing claims with the term “reacted” in them, even when they are not product by process claims. The Applicants contend that the patent office should not resort to a double standard, just to reject an application that should otherwise be allowed on the merits.

The Applicants further contend that the term “reacted” is a structural limitation rather than a “product by process” limitation. This is supported by case law, which will be discussed in detail below. It is very often that the inventor is not capable of identifying the exact structure of his/her invention, because of limitations of time and the inability to access expensive, sophisticated equipment that are often needed to analyze the final reaction products. The inventor is only aware of that he/she has an invention because of new properties noted in the product. The MPEP does not require the inventor to claim this new product by defining its properties. It can be claimed in terms of the two reactants that are used to form the product. Please see additional arguments below in regards to this matter.

In addition, conventions for naming new products often require several experts (from organizations such as the American Chemical Society or Chemical Abstracts) to gather together to name new products. The rules pertaining to the patentability of new inventions often do not allow the inventor the luxury of time for waiting for these experts to gather together to name a new chemical compound.

In addition, as noted above, case law holds that terms such as ‘reacted’ are structural limitations and should not be construed as “product by process” limitations. The courts have consistently held that a term that “can connote with equal force a structural characteristic of the product or a process of manufacture are commonly and by default interpreted in their structural sense, unless the patentee has demonstrated otherwise.” *3M Innovative Props. Co. v. Avery Dennison Corp.*, 350 F.3d 1365, 1371-72

(Fed. Cir. 2003). For example, the CCPA held that

[T]he recitation of the particles as ‘**interbonded one to another by interfusion between the surfaces of the perlite particles**’ is as capable of being construed as a structural limitation as ‘**intermixed,**’ ‘**ground in place,**’ ‘**press fitted,**’ ‘**etched,**’ and ‘**welded,**’ all of which at one time or another have been separately held capable of construction as structural, rather than process, limitations.

In re Garnero, 412 F.2d 276, 279 (C.C.P.A. 1969); see also *AFG Indus., Inc. v. Cardinal IG Co., Inc.*, 375 F.3d 1367, 1372-73 (Fed. Cir. 2004) (holding that the term ‘**multiple depositions**’ does not refer to a process but is only relevant if multiple depositions “affect the structure and optical properties” of the claimed material”); *Vanguard Prods. Co. v. Parker Hannifin Corp.*, 234 F.3d 1370, 1372 (Fed. Cir. 2000) (holding that the claim term “**integral**” describes a structural relation, not the particular manufacturing process related in the specification); *Hazani v. United States Int’l Trade Comm’n*, 126 F.3d 1473, 1479 (Fed. Cir. 1997) (“the ‘**chemically engraved**’ limitation, read in context, describes the product more by its structure than by the process used to obtain it.”).

The Applicants therefore contend that the term “reacted” is therefore not a “product by process” limitation but rather a “structural” limitation. For this reason at least, Silver does not teach all elements of the claimed invention. Since Silver does not teach all elements of the claimed invention, it cannot anticipate the claimed invention and the Applicants respectfully request a withdrawal of the § 102 rejection and the allowance of the claims.

Claims Rejected under 35 U.S.C. § 103

Claims 11 – 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of U.S. Patent No. 5,532,217 to Silver et al. (hereafter Silver) in view of U. S. Patent No. 5,711,960 to Shikinami (hereinafter Shikinami). (Office Action dated 10-03-08, page 4) The claims are drawn to a biocompatible composite comprising a biocompatible polymer, bioactive glass in the form of fibers that act as a scaffold. (Office Action dated 10-03-08, page 4)

In making the rejection, the Examiner has stated

As discussed above the '217 patent discloses a biocompatible composite comprising bioactive glass and a biocompatible polymer, the reference however is silent to the spacing of the fibers and their proximity to each other. The orderly arrangement of the fibers is common in the art as shown in the '960 patent. The '960 patent discloses a biocompatible scaffold comprising a biocompatible polymer and bioactive glass on the surface of the fibers (abstract). The biocompatible polymers include polyethylene and poly-glycolic acid fibers (col. 10, lin. 50-61). With these things in mind it would have been obvious to arrange the fibers of the '217 patent as seen in the '960 patent in order to improve implant stability and compression properties for implantation. It would have been obvious to apply the fiber arrangement with an expected result of a stable implantable composite useful in bone repair treatments.

(Office Action dated 10-03-08, page 4)

As noted above, Silver does not teach that not teach that the biocompatible polymer is reacted with the bioactive glass. The Examiner has also not pointed out where Silver teaches that the biocompatible polymer is reacted with the bioactive glass. Silver does not teach all elements of the claimed invention.

Shikinami teaches an implant material which has high mechanical strength and durability in three-dimensional directions. (see Abstract) Shikinami teaches that the implant material functions to synchronize with the deformation characteristics of surrounding biological tissues and is capable of being penetrated by biological tissues into its fabric space. (see Abstract)

Shikinami teaches that the implant material uses as a base material, a

biocompatible bulk structure of a three-dimensionally woven or knitted fabric of organic fibers or a composite fabric thereof, and its void ratio in the fabric is preferably set to 20 to 90 vol%. (see Abstract) The base material comprises a biocompatible bulk structure of a tri-axial or more three-dimensionally woven fabric of organic fibers, a tri-axial or more three-dimensionally knitted fabric of organic fibers or a combination thereof. (see Claim 1)

Shikinami in its Examples teaches the manufacturing of this three-dimensional woven fabric. Shikinami in Col. 7, line 25 through Col. 8, line 27 teaches how to manufacture a glass coated yarn. Only relevant portions of the disclosure of Shikinami are disclosed below to point out the differences between Shikinami and the claimed invention.

In its Example 1, Shikinami teaches that a high density polyethylene (HDPE) yarn of 50 denier filaments is coated with linear low-density polyethylene (LLDPE) (melted at 120°C), which is then subjected to a plasma treatment. (See Col. 17, lines 25 – 67) Following the plasma treatment, the yarn is subjected to treatment in a phosphate solution and a calcium containing solution to produce a thin layer of calcium phosphate on the yarn. (See Col. 18, lines 1 – 7) The yarn is then used to produce a three-dimensional weave of a block shaped orthogonal fabric. (See Col. 18, lines 8 – 20) The weave is then placed in a mold and pressurized following which it is coated with a fine particle powder of AW glass. (See Col. 18, lines 21 – 27)

Shikinami thus teaches manufacturing a weave from a yarn having a layer of calcium phosphate disposed on it with a layer of glass particles disposed upon the surface of the weave. Shikinami does not teach reacting a bioactive glass with a bioactive polymer; where the bioactive glass comprises calcium and phosphorus. The glass disclosed by Shikinami does not contain calcium or phosphorus. Additionally, the glass is not reacted with the polymer used in the yarn. For these reasons at least, Shikinami, like Silver, does not teach all elements of the claimed invention.

Thus, Silver, **even when combined with** Shikinami would not produce the claimed invention. Since neither Silver nor Shikinami teach all element of the claimed invention, there is no motivation to combine Silver with Shikinami.

The Examiner has contended that the Applicants have attacked the references

individually, and that one cannot show nonobviousness by attacking the references individually where the rejections are based on combinations of references. (Office Action dated 02-09-2009, page 6) The Applicants respectfully disagree.

The Applicants have not attacked the references individually except to show that the combination does not teach all elements of the claimed invention. In order to do this, the Applicants must point out to the Examiner what each reference does not teach and further to point out to the Examiner that when each reference does not teach the same claimed element of a particular invention, then the combination of references cannot be used in an obviousness rejection.

In this particular case, Silver does not teach that the biocompatible polymer is reacted with the bioactive glass. Shikinami must make up for this deficiency in order for the combination to teach all elements of the claimed invention. Shikinami however, does not. Thus while Shikinami may teach a composite comprising fibers in a scaffolding configuration, it must first teach a biocompatible polymer that is reacted with the bioactive glass to make up for the deficiency of Silver. Since it does not do so, the combination of references does not teach all elements of the claimed invention and the combination of references cannot be used in an obviousness rejection.

In summary, the Applicants believe that the Examiner has not made a prima facie case of obviousness over Silver when combined with Shikinami. The Applicants therefore respectfully request a withdrawal of the obviousness rejection over Silver in view of Shikinami.

It is believed that the foregoing amendments and remarks fully comply with the Office Action and that the claims herein should now be allowable to Applicants. Accordingly, reconsideration and allowance is requested.

If there are any additional charges with respect to this Amendment or otherwise, please charge them to Deposit Account No. 06-1130 maintained by Assignee.

Respectfully submitted,

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